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By Michael Sweeney*

I. INTRODUCTION

¶1 By transferring ownership rights of federally funded inventions to non-government contractors and their subsequent licensees, the University and Small Business Patent Procedures Act of 1980[1] (Bayh-Dole Act) gives private actors unprecedented rights to intellectual property that was cultivated with public money. This Comment discusses how shifting ownership rights for federally funded inventions from public agencies to the private sector affects what the taxpaying public receives in return for its investment. It also pinpoints ways to improve returns where inefficiencies exist through income sharing, open-licensing regimes, and a national tech transfer office.[2]

II. THE BAYH-DOLE ACT: PURPOSE AND PROBLEMS

¶2 The United States government invests many billions of dollars almost every year in scientific research.[3] By most metrics, federal funding is the largest bulwark for the United States' advancements in technology, medicine, and other vital fields. In 2007, the government funded roughly twenty-seven percent of basic research in the United States.[4]

¶3 The Bayh-Dole Act, passed three decades ago, was intended to promote the utilization of inventions arising from federally funded research or development.[5] Prior to Bayh-Dole, ownership rights of federally funded inventions predominantly went to the federal agency funding the research (such as the National Institute of Health (NIH) or the National Science Foundation (NSF)). However, federal agencies often left patents undeveloped and did not disseminate researchers' findings.[6] To ameliorate the agencies'

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* Many thanks to the tireless JTIP student editors. While I didn't always know who was providing the anonymous editorial comments, I do know they were greatly appreciated and helped immensely. Also, thank you to my constant inspirations: my parents, my three sisters, my girlfriend, and anyone else I'm lucky enough to call a close friend.

[1] University and Small Business Patent Procedures Act of 1980 (Bayh-Dole), 35 U.S.C. §§ 200–212 (2006).

[2] *See* discussion *infra* Parts V-A through V-C.

[3] Michael Yamaner, *Federal Funding of Basic and Applied Research Increases in FY 2009*, NAT'L CTR. FOR SCI. & ENG'G STATISTICS (Nat'l Sci. Found., Arlington, Va.), July 2011, *available at* http://www.nsf.gov/statistics/infbrief/nsf11324.pdf.

[4] *See* MARK BOROUSH, NAT'L SCI. FOUND., NATIONAL PATTERNS OF R&D RESOURCES: 2008 DATA UPDATE 28, tbl.6 (2010), *available at* http://www.nsf.gov/statistics/nsf10314/pdf/nsf10314.pdf.

[5] Patent and Trademark Amendments (Bayh-Dole Act), Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200–212).

[6] *See* Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1664, 1702 (1996).

neglect, Bayh-Dole provides a uniform system allowing the recipients of federal research funding, such as universities, to take title to inventions created using federal funds. To facilitate the transfer of ownership to funding recipients, Bayh-Dole requires that the inventor assign any inventions made using federal funds to the organization with which the inventor is affiliated (predominantly universities). From there, that organization can grant exclusive or non-exclusive licenses for these inventions at its discretion. In the 1980s, President Reagan issued both an executive memorandum[7] and an executive order[8] that extended this allowance for the assignment of rights to include large businesses.

¶4 Overall, scholars generally agree that Bayh-Dole is a clear improvement over the prior set of complex and non-uniform agency rules, simply because it created a standardized system of determining intellectual property ownership for federally funded research. Universities have certainly had some technology-transfer successes. The number of technology transfer offices at universities—which are in charge of registering and licensing researchers' patents—has increased substantially, and the number of patents they have filed has gone up at an even faster rate.[9]

¶5 However, this increase in private patent protection for federally funded inventions has also had some drawbacks. Since its passage in 1980, there have been highly critical reviews of Bayh-Dole's problems, countered by staunch defenses from its advocates. The disputes have led to extensive legislative tinkering by public officials.[10]

¶6 This debate has brought to light evidence which shows that universities are not always responsible caretakers of their intellectual property. Judge Lorelei Ritchie de Larena of the Trademark Trial and Appeal Board—and former Intellectual Property Manager at the University of California, Los Angeles—pinpoints the most common university missteps: "They get embroiled in research scandals without proper faculty monitoring; they regularly underreport technology-transfer activities to their federal sponsors; and they tend to drop even windfall income into a bureaucratic black hole."[11] Large percentages of tech-transfer revenue are directed towards university administration and do not go back to the researchers or entrepreneurs who actually commercialize the invention.[12] These critiques are not localized to any one type of tech-transfer office; mismanagement occurs at both public and private universities. Proponents argue that the Bayh-Dole Act has led to economic growth, particularly in the biotechnology industry.[13]

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[7] Memorandum on Government Patent Policy, 1 PUB. PAPERS 248 (Feb. 18, 1983).
[8] Exec. Order No. 12,591, 3 C.F.R. 220 (1988), *reprinted as amended in* 15 U.S.C. § 3710.
[9] *See* Richard R. Nelson, *Observations on the Post-Bayh-Dole Rise in University Patenting*, *in* INNOVATION POLICY IN THE KNOWLEDGE-BASED ECONOMY 165 (Maryann P. Feldman & Albert N. Link eds., 2001); *FAQs: Has There Been Growth in Academic Technology Transfer Programs*, ASS'N U. TECH. MANAGERS, http://www.autm.net/FAQs/2186.htm#4 (last visited Dec. 28, 2011).
[10] *See, e.g.*, National Technology Transfer and Advancement Act of 1995, Pub. L. No. 104-113, 110 Stat. 775 (1996) (codified as amended in scattered sections of 15 U.S.C.); Cooperative Research and Technology Enhancement (CREATE) Act of 2004, Pub. L. No. 108-453, 118 Stat. 3596 (amending 35 U.S.C. § 103(c) to address joint research agreements); Technology Transfer Commercialization Act of 2000, Pub. L. No. 106-404, 114 Stat. 1742 (amending the Stevenson-Wydler Technology Innovation Act of 1980 and the Bayh-Dole Act).
[11] Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 HOUS. L. REV. 1373, 1438 (2007).
[12] *Id.* at 1441.
[13] *See* Chester G. Moore, *Killing the Bayh-Dole Act's Golden Goose*, 8 TUL. J. TECH. & INTELL. PROP. 151, 155–57 (2006).

Critics counter that Bayh-Dole has negatively affected the practice and norms of science,[14] created "anticommons" problems, contributed to patent hold-ups,[15] and led to unnecessary increases in consumer prices.[16]

¶7 While university tech-transfer patent practices often line up with the intent of Bayh-Dole—helping to develop markets where federal agencies do not have the expertise or resources—these "contractors"[17] also often leave certain vital markets underserved, or completely neglected. Entire lines of inventions and products that could be of great use to taxpayers, such as green technologies,[18] are often owned by private players who may or may not find their development to be economically prudent. Meanwhile, many of the inventions that are developed are sold at a higher cost than they might have been if not for Bayh-Dole, when they would have automatically gone into the public domain.

¶8 This Comment does not intend to deride Bayh-Dole as a whole. It is readily apparent that the Act's underlying philosophy is sound. The point, rather, is to recognize where it has strayed from that philosophy and to help optimize its effectiveness going forward.

III. RIGHTS AND RESPONSIBILITIES UNDER BAYH-DOLE

A. Contractors' Rights and Responsibilities

¶9 Bayh-Dole applies to all research performed under a federal funding agreement, whether funded entirely or partially by the government.[19] The Act requires a written agreement between the federal agency and the contractor that contains the terms for the funding.[20] Under these terms, as stated above, Bayh-Dole allows recipients of federal research aid to choose to retain title to federally funded inventions. However, if exercising this option, the contractor must then abide by concomitant responsibilities. One responsibility is that funding recipients choosing to take title, including universities, are required to file a patent application in the United States and grant the government a "nonexclusive, nontransferable, irrevocable, paid-up license to practice . . . any subject invention throughout the world."[21] Bayh-Dole also requires that contractors take steps to commercialize any discoveries or inventions resulting from federally funded research, with the right to grant nonexclusive, partially exclusive, or exclusive licenses.[22] It further

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[14] *See* Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 109 (1999).

[15] These are both problems attributable to transaction costs: an anticommons occurs when too many intellectual property rights in basic research create obstacles for future research, and hold-ups occur when a patent holder impedes a product's development by demanding royalties.

[16] *See* Clifton Leaf, *The Law of Unintended Consequences*, FORTUNE, Sept. 19, 2005, *available at* http://money.cnn.com/magazines/fortune/fortune_archive/2005/09/19/8272884/index.htm.

[17] This term is used to refer to recipients of federal aid under Bayh-Dole.

[18] *See generally* Lisa Larrimore Ouellette, Comment, *Addressing the Green Patent Global Deadlock Through Bayh-Dole Reform*, 119 YALE L.J. 1727 (2010).

[19] *See* 35 U.S.C. § 201(b) (2006).

[20] *See id.* § 202.

[21] *Id.* § 202(c)(4); JENNIFER A. HENDERSON & JOHN J. SMITH, ACADEMIA, INDUSTRY, AND THE BAYH-DOLE ACT: AN IMPLIED DUTY TO COMMERCIALIZE 3 (2002), *available at* http://www.cimit.org/news/regulatory/coi_part3.pdf.

[22] *See* 35 U.S.C. § 202(c)(4); HENDERSON & SMITH, *supra* note 21, at 3.

demands that contractors preference United States industry for the manufacture of their inventions and favor small businesses for granting of exclusive licenses. Contractors are also required to report to the funding agency periodically, divide royalties or income generated from inventions with the inventors, and apply any undistributed income toward further research or educational ventures.[23]

B. Federal Agencies' Rights and Responsibilities

¶10 The Bayh-Dole Act, while giving contractors the option to elect rights to subject inventions, also grants the funding agencies significant rights. The Act grants federal agencies the power to "use rights [to the inventions] concurrently; [to] require or place restrictions on use by others; and [to], if provisions are not followed, actually require that title revert back to the government sponsor."[24]

1. March-in Rights

¶11 If the grantee does not adequately commercialize its federally funded inventions, Bayh-Dole includes provisions for the government to expropriate the invention. These provisions allow the funding agency to "march in" and assume ownership rights of intellectual property when certain parts of the Act have not been followed.[25] For example, if the contractor fails to "achieve practical application of the subject invention,"[26] the government may invoke the march-in right. Under the march-in provision, federal funding agencies can "require the contractor, an assignee or exclusive licensee" to grant a license, which can be either "nonexclusive, partially exclusive, or exclusive" and may be limited to a particular "field of use"[27] or the agency can grant the license itself.[28] To qualify and moderate these broad powers, the Act makes sure that any such compulsory license must be made "upon terms that are reasonable under the circumstances."[29]

2. Grant-back Rights

¶12 Funding agencies also maintain a grant-back of rights on every invention developed using federal research funds.[30] The grant-back secures government rights to "practice" the subject invention or have someone else practice the invention on the government's behalf. "The government's license under section 202(c)(4) does not provide the same ability to use the invention as the march-in authority. It is limited to practice 'for or on behalf of the United States,' whereas march-in authority is not so limited."[31]

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[23] *See* 35 U.S.C. § 202; HENDERSON & SMITH, *supra* note 21, at 3.
[24] Ritchie de Larena, *supra* note 11, at 1391 (footnotes omitted); *see also* 35 U.S.C. §§ 202(c)(4), 203, 204.
[25] 35 U.S.C. § 203.
[26] *Id.* § 203(a)(1).
[27] *Id.* § 203(a).
[28] *Id.*
[29] *Id.*
[30] *See id*. § 202(c)(4).
[31] Barbara M. McGarey & Annette C. Levey, *Patents, Products, and Public Health: An Analysis of the CellPro March-in Petition*, 14 BERKELEY TECH. L.J. 1095, 1114 (1999).

IV. DRAWBACKS ASSOCIATED WITH PRIVATE RIGHTS TO FEDERALLY FUNDED INVENTIONS

¶13 For better or worse, Bayh-Dole has led to a re-balancing of rights. When universities and other private contractors underutilize or improperly apply their Bayh-Dole responsibilities, taxpayers are often left footing the bill or are deprived of a potentially vital new technology (or both). The costs are varied and not always monetary. This Part discusses some of the ways in which the taxpaying public is not receiving sufficient returns on their investment in basic research.

A. Double Taxation

¶14 Double taxation occurs when the government spends tax dollars to develop an invention and then spends additional tax dollars (in the form of royalties) to use the invention in subsequently funded research.[32] While some inventions that would otherwise have gone unused in the hands of federal agencies are now developed because of the Act, "other inventions that would have been developed anyway are now being developed under the auspices of the Act."[33] Because of this, "these latter inventions now carry a 'tax' in the form of a royalty that subsequent researchers must pay to the patent holder, and this royalty is then passed on to the ultimate consumer, the public."[34] Insofar as these inventions would have been commercialized without the incentives provided by Bayh-Dole, the Act requires that the public pay more for something it otherwise would have obtained without private intermediaries.[35] In Committee debates, preceding passage of the Act, Senator Russell Long belabored this point, asking,

> Is this bill providing a limitation on just how much the successful contractor can charge the public for what the public has already paid for?
>
> . . . .
>
> . . . . Is there any limitation in this proposal as to how much he could charge the public to have the benefit of what the public had already paid for when they paid for the research?[36]

Some acknowledge that before the Act the public was forced to pay once and received nothing, but disagree with Senator Long's position on the ground that at least now the public receives some benefit, in the form of commercial products, even though they pay twice.[37] Still, there are better alternatives, as discussed below.

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[32] *See* Gary Pulsinelli, *Share and Share Alike: Increasing Access to Government-Funded Inventions Under the Bayh-Dole Act*, 7 MINN. J.L. SCI. & TECH. 393, 443 (2006).
[33] *Id.* at 395.
[34] *Id.*
[35] *Id.*
[36] *Patent Policy: Hearings on S. 1215 Before the Subcomm. on Sci., Tech., & Space of the S. Comm. on Commerce, Sci., & Transp.*, 96th Cong. 392 (1979) [hereinafter *Patent Policy Hearings*] (statement of Sen. Russell B. Long, Member, S. Comm. on Commerce, Sci., & Transp.).
[37] *See* Pulsinelli, *supra* note 32, at 443.

B. Anticommons

¶15 Under a theory of anticommons, a property may be underused if too many people have the right to exclude others from using it. In Bayh-Dole's tech transfer context, anticommons occur when too many patent rights are being awarded in certain fields to universities and other non-governmental entities, and these patents are interfering with the progress of research in these areas.[38]

¶16 In many ways the same problem that occurred before Bayh-Dole—underutilization of vital products—still occurs, only now the inventions are monopolized in private hands rather than disregarded by public agencies. According to Stanford Law Professor and intellectual property specialist Mark Lemley, "While in theory patents spur innovation, they can also interfere with it. Broad patents granted to initial inventors can lock up or retard improvements needed to take a new field from interesting lab results to commercial viability."[39] Developers increasingly pass over "follow-on" inventions[40] because universities locked up the foundational inventions.[41] These collections of over-patented technologies are known as "patent thickets."[42] Although the Act provides important incentives for getting many inventions developed, some inventions would have been developed even without the incentives of the Bayh-Dole Act and are now less available because of it.[43]

¶17 Universities have licensing practices particular to their needs that can often exacerbate anticommons.[44] For example, universities rarely cross-license, whereas manufacturing entities typically do. When two manufacturers cross-license with each other and one competitor sues the other manufacturer for infringement, the other manufacturer can often countersue. However, because universities are non-manufacturing entities, they do not trade their patents away for cross-licenses. Universities are not concerned with receiving licenses to other people's patent rights because they do not need to develop competing technologies. Therefore, technology developers interested in licensing from universities can only respond to a suit, with little ability to countersue.

¶18 Secondly, universities generally grant exclusive licenses over non-exclusive licenses.[45] Because exclusive licenses allow tech transfer offices to charge higher fees to licensees who want to have sole ownership rights to an invention, they generate higher revenue and enable universities to pay the costs of patent prosecution.[46] However, exclusive licenses also block competitors from developing the invention.

¶19 Finally, universities are increasingly enforcing their patents:

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[38] *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698 (1998).
[39] Mark A. Lemley, *Patenting Nanotechnology*, 58 STAN. L. REV. 601, 618–19 (2005) (footnote omitted).
[40] *Id.* at 627.
[41] Jacob H. Rooksby, *University Initiation of Patent Infringement Litigation*, 10 J. MARSHALL REV. INTELL. PROP. L. 623, 637 (2011).
[42] *See id.*
[43] *See* Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289 (2003).
[44] *See id.*
[45] Lemley, *supra* note 39, at 626.
[46] However, there is debate as to whether exclusive licenses lead to higher *long-term* revenue. *See* Mark A. Lemley, *Are Universities Patent Trolls?*, 18 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 611, 617 (2008).

> Recent years have seen high-profile cases litigated to judgment by the University of California, the University of Rochester, Harvard, MIT, Columbia, Stanford, and suits filed by many other universities. . . .
>
> Universities, recognizing patent licensing and litigation as an important revenue source in the modern environment, have been active in politics . . . in opposing most of the effective pieces of draft patent reform legislation.[47]

In the end, these licensing practices lead to patent hold-ups, wherein "a patent-holder impedes [a product's] development by demanding royalties."[48] Although the purpose of patents *is* to give the patent-holder the right to impede others' use of the invention (i.e., a monopoly), this result seems questionable when taxpayers funded the invention and universities are left with the monopoly.

C. High Cost

¶20 One econometric analysis, using data on academic licensing revenues from 1998–2002, suggests that after subtracting the high costs of patent management, net revenues earned by U.S. universities from patent licensing were "on average, quite modest"[49] nearly three decades after Bayh-Dole took effect. Seeing this trend, some commentators have suggested that heavily patent-leaning "universities should form a more realistic perspective of the possible economic returns from patenting and licensing activities."[50]

¶21 Because of this high cost, only a handful of universities make substantial profits from their tech-transfer offices.[51] While this might suggest that the universities outside of these few that profit handsomely should be doing *more* patenting, trying to squeeze as many inventions out of their intellectual property portfolios as possible, it is just as likely a sign that they are *over*-patenting, spending significant time and resources managing patents that do not generate enough revenue to cover their overhead.

D. Under-reporting

¶22 Under § 202 of Bayh-Dole, the funding recipient must comply with various disclosure and reporting requirements to retain rights to the invention, including reporting the existence of the invention to the government agency[52] and keeping the agency apprised of progress toward patenting and utilizing the invention.[53]

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[47] *Id.* at 618.
[48] Lisa Larrimore Ouellette, Note, *How Many Patents Does It Take to Make a Drug? Follow-on Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOMM. & TECH. L. REV. 299, 308 n.58 (2010).
[49] Harun Bulut & GianCarlo Moschini, *U.S. Universities' Net Returns from Patenting and Licensing: A Quantile Regression Analysis* 13 (Ctr. for Agric. & Rural Dev., Iowa State Univ., Working Paper No. 06-WP 432, 2006), *available at* http://www.card.iastate.edu/publications/DBS/PDFFiles/06wp432.pdf.
[50] *Id.* at 14; *see also* Anthony D. So et al., *Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience*, 6 PUB. LIBR. SCI. BIOLOGY 2078, 2079 (2008).
[51] Bulut & Moschini, *supra* note 49, at 2.
[52] 35 U.S.C. § 202(c)(1) (2006).
[53] *Id.* § 202(c)(5).

¶23 In reality, many recipients of federal funding do not abide by these reporting requirements.[54] While the U.S. Department of Commerce is in charge of policing tech-transfer activity, sanctions for failing to report inventions lack clarity, and their enforceability is difficult.[55] The U.S. Government Accountability Office (GAO) has concluded that, under the current structure, it is not logistically possible to decipher whether universities are fulfilling their obligations under the Act and that government agencies must rely on universities to report their findings, since there are no established enforcement mechanisms.[56]

¶24 It is, therefore, up to each university to let the federal government know whether they are fulfilling their duty to commercialize. So far, they have failed to do so adequately. Under Bayh-Dole, the U.S. Patent and Trademark Office "should have two independent records of the government's rights to a federally sponsored invention—the government interest statement on the patent and the confirmatory license recorded in the Government Register."[57] According to the GAO's findings, research contractors complied with both reporting requirements *only six percent* of the time.[58]

¶25 The importance of reporting compliance should not be understated. When research institutions do not disclose their federally funded inventions, it is impossible for the respective agencies to utilize grant-back or march-in rights on taxpayers' behalf.[59] As stated above, a grant-back allows government researchers to freely utilize federally funded inventions without paying for licenses. However, without access to or knowledge of which university inventions federal agencies should have rights to, a grant-back is toothless.

E. Conflicts of Interest

¶26 Since Bayh-Dole heavily incentivized academic ties between federally funded researchers and private industry, "academic commercialism" has been much more prevalent in higher learning. Professors and other researchers commonly have financial incentives interwoven with their purely academic pursuits.[60] Because of this trend, there

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[54] *See* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-99-242, TECHNOLOGY TRANSFER: REPORTING REQUIREMENTS FOR FEDERALLY SPONSORED INVENTIONS NEED REVISION 14 (1999) [hereinafter REPORTING REQUIREMENTS], *available at* http://www.gao.gov/archive/1999/rc99242.pdf.

[55] Scott D. Locke, Esq., *Patent Litigation over Federally Funded Inventions and the Consequences of Failing to Comply with Bayh-Dole*, 8 VA. J.L. & TECH. 3, 5, 27 (2003).

[56] *See* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-98-126, TECHNOLOGY TRANSFER: ADMINISTRATION OF THE BAYH-DOLE ACT BY RESEARCH UNIVERSITIES 5 tbl.1, 16 (1998), *available at* http://www.gao.gov/archive/1998/rc98126.pdf.

[57] *See* REPORTING REQUIREMENTS, *supra* note 54, at 6.

[58] *See id.*

[59] Ritchie de Larena, *supra* note 11, at 1398 ("While underreporting may seem relatively innocuous, and merely due to benign neglect, it means that federal taxpayers are not even getting basic governmental access to many of the inventions they fund.").

[60] JENNIFER WASHBURN, CTR. FOR AM. PROGRESS, BIG OIL GOES TO COLLEGE: AN ANALYSIS OF 10 RESEARCH COLLABORATION CONTRACTS BETWEEN LEADING ENERGY COMPANIES AND MAJOR U.S. UNIVERSITIES 12, 36 (2010), *available at* http://www.americanprogress.org/issues/2010/10/pdf/big_oil_If.pdf ("Today it is common for both U.S. universities and their professors to have direct financial interests in their own campus-based research (through patents, licenses, equity stakes in new companies, and royalty agreements). Many individual

are concerns that the ethos of academic institutions may be shifting, depriving students and the public of the objective, independent research usually expected in a university environment.

¶27 This increased commercialism is often paradoxically in unison with some parts of Bayh-Dole, while being in direct conflict with other provisions. For example, the Act directly promotes partnerships between academia and industry, but, as stated above, it also requires recipients of federal aid to "favor U.S. industry for the manufacture of inventions, and small businesses for the granting of exclusive licenses."[61] Yet, despite this requirement, many universities have increasingly shown a desire to partner with large, foreign corporations for research grants.[62] These partnerships, which are often intermingled with federally funded grant projects, raise questions about who should own the resulting invention—the university or the corporation. If the parties agree to give full ownership to the corporations, then they are directly violating the Act's provisions favoring "small businesses" and "U.S. industry."

¶28 The largest (and possibly most contentious) deal of this kind is British Petroleum's (BP) $500 million renewable energy research initiative.[63] The initiative partners two of the largest and most venerable public research institutions, UC Berkeley and the University of Illinois, with an oil conglomerate, BP. Deals like these between academia and large profit-driven corporations, while not specifically encouraged by Bayh-Dole, are much more common since its passage and raise a great deal of ire amongst research traditionalists. BP's recent oil spill has made the project's goals even more opaque and added an even higher level of public scrutiny.[64]

V. CASE STUDY: THE PHARMACEUTICAL INDUSTRY

¶29 A real-life example may best illustrate some of the drawbacks to Bayh-Dole stated in Part IV. In 1990, Mary-Claire King, a cancer expert at UC Berkeley, published research stating that there was a "breast cancer susceptibility gene" on Chromosome 17.[65] A number of research groups simultaneously began sifting through more than thirty million base pairs of nucleotides, trying to help locate the exact location of this gene.[66] In the spring of 1994, a team led by Mark Skolnick at the University of Utah was able to identify the gene's exact location—marginally beating out its competitors—finding a gene with 5,592 base pairs and codes for a protein that was 1,900 amino acids long.[67]

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professors also have extensive personal financial ties to companies that sponsor their own academic research . . . .").

[61] HENDERSON & SMITH, *supra* note 21, at 3.

[62] *See generally* WASHBURN, *supra* note 60, at 31.

[63] *See* Robert Sanders, *BP Selects UC Berkeley to Lead $500 Million Energy Research Consortium with Partners Lawrence Berkeley National Lab, University of Illinois*, UC BERKELEY NEWS (Feb. 1, 2007), http://berkeley.edu/news/media/releases/2007/02/01_ebi.shtml.

[64] Terence Chea, *UC Berkeley's BP Deal Tainted by Oil Spill: $500 Million Research Agreement at Stake*, HUFFINGTON POST (July 31, 2010, 3:27 PM), http://www.huffingtonpost.com/2010/07/31/uc-berkeleys-bp-deal-tain_n_666355.html.

[65] Leaf, *supra* note 16.

[66] *Id.*

[67] *Id.*

Skolnick's team immediately filed a patent application and obtained sole title to the discovery in 1997.

¶30 The science leading to Skolnick's discovery was very much a collective effort. There is evidence that the "NIH had funded scores of investigative teams around the country and given nearly 1,200 separate research grants to learn everything there was to learn about the genetics of breast cancer."[68] Yet, after Skolnick's team received the patent, they refused to license the necessary technology to other cancer treatment companies and insisted on doing all U.S. testing for the presence of mutations in the gene, even though patients with the mutation have as high as an eighty-six percent chance of getting cancer.[69] They maintained their screening price at $2,975 for the analysis.[70]

¶31 This type of restrictive licensing occurs regularly, despite the fact that many of the companies reaping the profits are highly dependent on research performed by government-funded scientists. The end result is vastly higher drug prices and health insurance. In 2003, Americans spent $179 billion on prescription drugs, up from $12 billion in 1980.[71] This amounts to a thirteen percent increase *each year* for two decades. These costs apply to individuals not only as patients, but also as taxpayers, because "[t]he U.S. government picks up the tab for [the healthcare of] one in three Americans by way of Medicare, Medicaid, the military, and other programs."[72]

¶32 American pharmaceuticals have profited greatly from the government benefits provided under Bayh-Dole. Coupled with their preferential tax treatment, pharmaceuticals are receiving double doses of federal aid. One analysis concluded "that pharmaceutical makers have one of the lowest effective tax rates and one of the highest after-tax profit rates of any industry."[73]

¶33 Meanwhile, the American public has received poor returns on their direct financial investments in health care research and development:

> Indeed, in the years 1985 through 1994, NIH received slightly less than $76 million in royalties, $40 million of which came from a single license for the HIV antibody test kit. From 1993 through 1999, royalties reached a total of nearly $200 million, reaching $45 million in 1999. But that figure still represents less than one percent of NIH's funding for 1999.[74]

Yet, for some reason, despite these skyrocketing costs and poor returns on investment, government agencies refuse to exercise their royalty-free use rights for federally funded inventions.

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[68] *Id.*
[69] *Id.*
[70] *Id.*
[71] *Id.*
[72] *Id.*
[73] David Halperin, *The Bayh-Dole Act and March-In Rights*, OFF. TRANSFER TECH. 10 (Mar. 2001), http://www.ott.nih.gov/policy/meeting/David-Halperin-Attorney-Counselor.pdf.
[74] *Id.*

VI. STRATEGIES FOR GETTING THE TAXPAYERS A BETTER RETURN ON THEIR INVESTMENT

A. Alternative (but Unworkable) Proposals

¶34 A number of different proposals have attempted to counteract the increasingly private monopolization of scientific findings funded by public money. Some have argued for expanding copyright's fair use doctrine to patent law.[75] Others have argued for the expansion of the experimental use exception (particularly in the wake of *Madey v. Duke*[76]). A few have argued for prohibiting certain upstream patents or for ex ante, "reach-through" compulsory licenses to counteract patent thickets.[77] This debate is particularly acute today in relation to the patentability of genes.[78] Another proposal suggests that Congress should amend Bayh-Dole to "t[ie] socially responsible licensing practices to federal research grants," especially for the dissemination of green technologies in developing nations.[79] One more proposal, by Rochelle Dreyfuss, suggests a system in which non-profit researchers can use any patented technology if they sign a waiver requiring their "institution to promptly publish the results of work conducted with the patented technology and to refrain from patenting discoveries made in the course of that work."[80]

¶35 However, while these proposals may each have merit in certain contexts, they are all over- or under-inclusive in addressing the inequalities created by Bayh-Dole. Take, for example, Dreyfuss's proposal. While it recognizes the significant difference between public and private sector science and counteracting the special treatment universities receive as non-profits, the proposal would likely meet heavy industry resistance and create disincentives for firms wanting to develop vital technologies.[81]

B. Optimal Solutions

¶36 The ensuing discussion combines three preferred strategies for recovering research costs for the taxpayer. These proposals are specifically tailored to Bayh-Dole and are more viable than the alternatives discussed above.

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[75] *See* Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1198–1211 (2000).
[76] Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002).
[77] *See* Richard Li-dar Wang, *Biomedical Upstream Patenting and Scientific Research: The Case for Compulsory Licenses Bearing Reach-Through Royalties*, 10 YALE J.L. & TECH. 251 (2008).
[78] *See* Ass'n for Molecular Pathology v. United States Patent & Trademark Office, 702 F. Supp. 2d 181, 232 (S.D.N.Y. 2010); *see also* Andrew Pollack, *In a Policy Reversal, U.S. Says Genes Should Not Be Eligible for Patenting*, N.Y. TIMES, Oct. 30, 2010, at B1.
[79] Ouellette, *supra* note 18, at 1735.
[80] Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457, 471 (2004).
[81] Aaron Miller, *Repairing the Bayh-Dole Act: A Proposal for Restoring Non-Profit Access to University Science*, 2005 B.C. INTELL. PROP. & TECH. F. 093001, http://www.bc.edu/bc_org/avp/law/st_org/iptf/articles/content/2005093001.html.

1. Universities Share a Percentage of Federally Funded Licensing Income with Their Federal Sponsors

¶37 Universities that make "windfall" profits with the help of federal aid should be required to pay some of that revenue back to their sponsoring agency. This practice existed prior to Bayh-Dole and still exists in some forms today.[82] For example, as recently amended in the new Leahy-Smith America Invents Act, "Government-owned-contractor-operated facilities" are expected to pay 15% of any excess in profits over 5% of their annual budget back to the Treasury.[83] However, the provisions in Section 202(c)(7) currently do not apply to universities.[84] Moreover, section 204 of the original Bayh-Dole bill allowed the government to recoup part or all of its investment in research and development after the invention generated specified amounts of profit.[85] Senator Thurmond, an original sponsor of the bill, considered this provision "[p]erhaps the most significant feature of th[e] bill."[86] Although this provision does not appear in the final version of the bill, it was in the Senate-passed version and is directly in concert with much of the Act's overall intent.

¶38 Further legislative testimony directly "link[s] the invocation of march-in rights to the existence of 'windfall profits' on a subject invention."[87] The U.S. Comptroller General at the time, in a written response to the Senate, relayed that the Department of Energy "said that march-in rights to protect the public's interest were developed to take care of and address the patent policy issues of *contractor windfall profits*, suppression from granting contractors rights to inventions."[88] Former General Patent Counsel for General Electric testified as to march-in rights, "We think it is part of the answer to the so-called windfall situation."[89]

¶39 Except for approximately ten tech-transfer hotbeds,[90] most universities do not generate enough tech-transfer income to be significantly burdened by a larger "windfall sharing" requirement. Further, the most profitable universities that would be taxed the most heavily are also the ones with the largest endowments[91]—endowments fueled, in

[82] *See* Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 TUL. L. REV. 631, 663 (2001).
[83] Leahy-Smith America Invents Act, Pub. L. 112-29, § 13, 125 Stat. 327, (2011) (amending 35 U.S.C. § 207(c)(7)(E)(i)).
[84] Ritchie de Larena, *supra* note 11, at 1388.
[85] *See* S. REP. NO. 96-480, at 34 (1979).
[86] *The University and Small Business Patent Procedures Act: Hearings on S. 414 Before the S. Comm. on the Judiciary*, 96th Cong. 34 (1979) [hereinafter *University and Small Business Patent Hearings*] (statement of Sen. Strom Thurmond, Member, S. Comm. on the Judiciary).
[87] Halperin, *supra* note 73, at 7.
[88] *University and Small Business Patent Hearings*, *supra* note 86, at 56 (statement of Elmer B. Staats, Comptroller Gen. of the United States) (emphasis added).
[89] *Patent Policy Hearings*, *supra* note 36, at 317 (statement of Harry F. Manbeck, Jr., General Patent Counsel, General Electric Co.).
[90] Leaf, *supra* note 16.
[91] NAT'L ASS'N OF COLL. & UNIV. BUSINESS OFFICERS, U.S. AND CANADIAN INSTITUTIONS LISTED BY FISCAL YEAR 2009 ENDOWMENT MARKET VALUE AND PERCENTAGE CHANGE IN ENDOWMENT MARKET VALUE FROM FY 2008 TO FY 2009 (2010), *available at* http://www.nacubo.org/Documents/research/2009_NCSE_Public_Tables_Endowment_Market_Values.pdf.

part, by licensing revenues from their tech-transfer activities.[92] Although it is true that they would be taxed the most heavily because of their relative success, there should be little concern about their ability to withstand giving back some of the profits generated off the public dole.

2. Researchers Supported by Federal Funds Should Have Licenses to Make and Use for Research Purposes All Inventions Developed with Federal Funds

¶40 This proposal, first suggested by Professor Gary Pulsinelli,[93] essentially embodies and animates the grant-back rights in Bayh-Dole's § 202(c)(4). Regardless of commercial licensing status, government contractors should utilize the access Bayh-Dole gives them to every publicly funded invention for undertaking government research or procurement. This would help to "realiz[e] the government's Bayh-Dole grant-back to its fullest potential."[94]

¶41 This grant-back proposal could be used to benefit the public in three important ways.[95] First, government scientists could use the license to conduct research without the need for a paid license.[96] Second, other government contractors, such as university recipients of federal funds, could use the license in follow-on research, or even independent research, where rights to an underlying invention might be particularly useful.[97] Third, the government could use the grant-back to procure inventions on its behalf. For example, it could receive less expensive versions of pharmaceuticals administered through the Medicare or Department of Veterans Affairs programs.[98]

¶42 Another positive effect of this proposal is that under-reporting of inventions by tech-transfer offices would be less of a concern. Rather than waiting for universities to report their findings and monitor the by-products of their efforts, the impetus would fall on universities to *stop* government researchers from using their inventions. There would be a presumption in favor of government workers using any university inventions to which they can get access. Further, it would cut back on the "double-taxation" phenomenon—when government agencies fund an invention and then pay for the rights to use that invention in subsequent research, as discussed above. If government funded researchers had a royalty-free license to use all government-developed technology for research purposes, then this "tax" would be substantially eliminated.

3. Underutilized Patents Should Be Placed in the Public Domain and a National Technology Transfer Office Should Monitor Their Usage To Facilitate Partnerships

¶43 Anticommons are the result of over-patenting, where private actors have rights beyond their needs. Therefore, the best way to counteract the deleterious effects of

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[92] Press Release, U.S. Patent & Trademark Office, USPTO Releases List of Top 10 Universities Receiving Most Patents in 2005 (Apr. 6, 2006), http://www.uspto.gov/news/pr/2006/06-24.jsp.
[93] Pulsinelli, *supra* note 32, at 442.
[94] Ritchie de Larena, *supra* note 11, at 1443.
[95] *Id.* at 1395.
[96] *Id.*
[97] *Id.*
[98] *Id.*

under-used, privatized patent pools would be to place those patents that are not being commercialized into the public domain.

¶44 Judge Ritchie de Larena wrote one of the seminal articles illustrating this plan.[99] In § 202(c)(5), the Act already gives federal agencies the right to require "periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees."[100] This reporting requirement implies that contractors must take necessary steps to commercialize any discoveries or inventions resulting from federally funded research. Failure to do so should result in cession of the patent over to public use. This should not adversely affect the patent owners in the long run, because if the patent has true potential, the private owner will certainly take steps to cultivate it, and, if it does not, the private owner should not mind that it is being ceded to public use.

¶45 Although it initially will cause tech-transfer offices to lose some sunk costs for those patents that they have already spent money procuring, they should quickly develop ways to tell if a patent is marketable and, if not, leave their findings open to royalty-free licensing. This could look something like a creative commons license,[101] wherein credit for the initial discoveries would still go to the researchers and institutions that made the breakthrough, but others could simultaneously use and develop the information free of charge.

¶46 In conjunction with the placement of underused patents in the public domain, a national technology transfer office should be established to act as a clearinghouse for parties that may be interested in developing them. As such, the national office could facilitate joint partnerships between research institutions looking to commingle their patent pools. Where many patents for minor inventions are relatively useless in the hands of one institution, many pools of minor inventions could become quite valuable if coalesced and opened up to every type of government researcher.

¶47 The U.S. GAO is in charge of monitoring Bayh-Dole implementation and determining when to allow the government to assert ownership control over federally funded inventions.[102] Because the GAO already monitors and periodically reports on the Act's implementation, maintaining a database of underutilized, federally funded inventions should be entirely within its purview.

¶48 If not administered by the GAO, then a national, independent tech-transfer office could also lend increased accountability and monitoring of existing patent portfolios, acting as a watch dog to ensure that universities are fulfilling their contractual Bayh-Dole responsibilities. For example, an independent, national tech-transfer office could monitor incoming revenue from university licensing deals to make sure it is funneled back into research, as required under § 202(c)(7). This could also help combat many of the conflicts of interest that currently exist by preventing revenue from improperly going back to the university's administration, endowment, or partnered corporations. A

[99] *Id.* at 1437–44.
[100] 35 U.S.C. § 202(c)(5) (2006).
[101] *See About the Licenses*, CREATIVE COMMONS, http://creativecommons.org/licenses/ (last visited Dec. 28, 2011).
[102] U.S GOV'T ACCOUNTABILITY OFFICE, GAO-09-742, FEDERAL RESEARCH: INFORMATION ON THE GOVERNMENT'S RIGHT TO ASSERT OWNERSHIP CONTROL OVER FEDERALLY FUNDED INVENTIONS 1 (2009), *available at* http://www.ott.nih.gov/PDFs/GAOreportTT.pdf.

national tech-transfer office could also open the door to more extensive use of march-in rights.

VII. COUNTER ARGUMENTS

A. Fifth Amendment Takings

¶49 Patent owners might counter that invoking the grant-back or "march-in" provisions and seizing a patent on behalf of the public would constitute an unjust taking under the Fifth Amendment.[103] The owners might argue that their research added value after receiving federal funds, and, by putting in the necessary work, they should receive full rights to the inventions. However, the counter to this is that Bayh-Dole firmly establishes both march-in and grant-back rights, and, because patent owners are bound to the Act's provisions by virtue of their willful contractual agreement, they essentially concede that the Fifth Amendment should not apply.

B. Deference to the Private Sector

¶50 Another critique of these proposals is that once the government disburses funds, development should be left to the private sector; allowing government researchers and the public free access to inventions disincentivizes private research and development investments. However, that too is an unfounded concern.

¶51 First of all, the vast majority of funding recipients are universities or research institutions whose fundamental priorities should not be enhancing their patent pool, but advancing their respective fields of endeavor. With or without endless patent portfolios, universities will perform research. They did so before Bayh-Dole was enacted, and they have continued to do so. Invoking march-in and other provisions of the Act for the public benefit likely will not change that.

¶52 Second, as stated above, many tech-transfer offices do not garner huge returns for their universities. Patent management nowadays—in contrast to the practice prior to Bayh-Dole, when most discoveries passed into the public domain—is very much a "lottery" based system: "[e]ven though most university inventions are never picked up by a licensee, and even fewer generate big income, there is the constant 'lottery' effect whereby technology-transfer offices take a risk in paying patent expenses on what they hope will be the big winner."[104] Therefore, the vast majority of patents are applied for in the hopes that they will "win" big. However, it should be relatively clear within a short period of time that an invention will not be the big winner every tech-transfer office hopes for. By extracting those patents and turning them over to the public, tech-transfer revenues will likely suffer little to no effect, and the offices may learn to better utilize scarce funds to only apply for patents on those inventions they truly *know* are valuable.

¶53 Finally, the two proposals stated in Part VI do not take away the big "winners" in tech-transfer. The first proposal simply grants government researchers or their affiliates

[103] *See* U.S. CONST. amend. V.

[104] Ritchie de Larena, *supra* note 11, at 1381–82 (footnotes omitted); *see also* Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. PA. L. REV. 1, 24 (2005).

the right to *use* an invention, not take it away, and the second proposal would only affect the "loser" patents, those that are left undeveloped.

C. Tech-Transfer Offices Actually Save Taxpayers Money

¶54 Some argue that revenue from university-owned patents often goes toward funding more research, reducing the need for government funding and thereby funding research by taxing those using the technology, rather than the population in general.

¶55 For one, the truth of this argument is debatable. While it is true that greater revenue from tech-transfer could be used to fund more research and decrease the need for taxpayer money, there is little evidence this actually occurs in practice. A large percentage of the indirect costs and Bayh-Dole income "go[es] into a black hole of university administration, which may or may not provide any clear payback to the funding public, or for that matter, to the university community including students who see rising tuition every year."[105] Nothing provides universities with instructions on how to spend their licensing income; university administrators frequently do not even know how this money is spent.[106] Therefore, to trust universities to abide by the Act's requirement that licensing income be earmarked for "scientific research or education"[107] without providing any way to monitor that this is actually occurring, is wishful thinking.

¶56 Secondly, taken to its extreme, this argument basically implies that if tech-transfer offices were successful enough, federal funding would not be necessary—an argument universities would likely never make. Federal aid is too much of a cash-cow, and too engrained in their cost structure, for them to claim that they can go it on their own.

D. Sharing Income with Funding Agencies Could Influence Future Research Grants

¶57 If universities were forced to share their Bayh-Dole licensing revenue with their funding agencies, one concern is that this might incentivize the agencies to only fund research that can be commercially licensed and neglect basic research that cannot be monetized.[108] However, "if that were the case then [agencies like] the NIH would already have an incentive to fund more applied rather than basic research today, since applied research tends to get more press and public attention in licenses."[109] However, there is evidence to the contrary, showing that, while NIH funding for both basic applied research increased in the last few decades, basic had a greater actual and proportional increase.[110]

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[105] Ritchie de Larena, *supra* note 11, at 1411 (footnotes omitted).
[106] Jeffrey Brainard, *The Ghosts of Stanford: Have Federal Constraints on Reimbursing Overhead for Research Grants Gone Too Far?*, CHRON. HIGHER EDUC., Aug. 5, 2005, at A16.
[107] 35 U.S.C. § 202(c)(7)(C) (2006).
[108] Ritchie de Larena, *supra* note 11, at 1441 n.460.
[109] *Id.*
[110] *Compare* RONALD L. MEEKS, NAT'L SCI. FOUND., FEDERAL FUNDS FOR RESEARCH AND DEVELOPMENT: FISCAL YEARS 1973–2003; FEDERAL OBLIGATIONS FOR RESEARCH TO UNIVERSITIES AND COLLEGES BY AGENCY AND DETAILED FIELD OF SCIENCE AND ENGINEERING 65 tbl.2G (2004), *available at* http://www.nsf.gov/statistics/nsf04332/pdf/nsf04332.pdf (detailing basic research), *with id.* at 101 tbl.3G (detailing applied research).

VIII. CONCLUSION

¶58 The legislative intent behind Bayh-Dole was to promote an "Academic-Industrial Complex."[111] Much like the infamous military-industrial complex, Bayh-Dole was meant to foster ties between vital sectors of the U.S. economy—universities and federal agencies—and stimulate scientific advancement in the process. There is no doubt that "the importance of linking our unparalleled network of over 700 Federal laboratories and our Nation's universities with United States industry continues to hold great promise for our future economic prosperity."[112]

¶59 However, federal agencies have not always received adequate compensation for their investments in this relationship, and, in an era like the present, where federal deficits are a cause of great consternation, the U.S. government literally cannot afford to throw money at projects without receiving any return. As discussed above, there are a number of technology sectors where increased federal funding has not led to the anticipated public benefit.

¶60 To quote Judge Ritchie de Larena:

> [I]f universities misuse research funds, bungle licensing deals, or simply overlook important technologies that are vested in them by the Bayh-Dole Act, then taxpayers are not receiving that deserved benefit.
>
> . . . .
>
> From an equity perspective, surely partial, if not full, payback to the funding public seems eminently fair. If indeed the intent of the patent system at large is to reward—and thereby encourage—investment in the creation of new inventions, then it naturally follows that the reward for inventions created with federal research funds should inure to the federal taxpayers who paid for them. However, under the current regime, universities have no incentive—or even any mechanism—to try to recover any costs for their government sponsors.[113]

A rebalancing of ownership rights, licensing revenues and experimental use towards the federal side of the university–federal agency ledger could substantially benefit the taxpayers and would steer closer to the intended purpose of the Bayh-Dole Act.

¶61 Three suggestions, espoused in some form by a number of tech-transfer academics, are proffered here. First, a percentage of Bayh-Dole tech-transfer income should be sent back to federal funding agencies. Second, any researcher receiving federal funds should be allowed to use, for research purposes, all inventions developed with federal money. Finally, underutilized patents should be placed in the public domain to be monitored and exchanged through a national tech-transfer office. Implementing these three changes could go a long way to giving the taxpayer direct returns on some of the many billions of dollars spent every year on research in the United States.

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[111] Felicia R. Lee, *Academic Industrial* Complex, N.Y. TIMES, Sept. 6, 2003, at B9; *see generally* Eyal Press & Jennifer Washburn, *The Kept University*, ATLANTIC, Mar.2000, at 39–40, *available at* http://www.theatlantic.com/magazine/archive/2000/03/the-kept-university/6629/.

[112] Technology Transfer Commercialization Act of 2000, Pub. L. No. 106-404, § 2(1), 114 Stat. 1742.

[113] Ritchie de Larena, *supra* note 11, at 1387, 1389 (footnotes omitted).